

Remarks

Reconsideration of the application, as amended, is respectfully requested.

Claim 4 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention, the examiner noting that "C.P." was unclear. Claim 4 has been amended to call for commercially pure titanium with a corresponding clarification placed in paragraph 013 (now paragraph 013.1). It is therefore believed that the rejection has been obviated.

Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Deutchman et al. (U.S. Pat. No. 4,992,298) in view of Cotell et al. (U.S. Pat. No. 5,242,706). In the rejection, the examiner notes that Deutchman et al. teach a dual ion beam ballistic alloying process and describes the several steps of cleaning the surface of the substrate with a first energy beam, depositing material on the substrate with a low energy sputtered beam, simultaneously exposing the substrate to said first energy beam with a high energy to grow a ballistically alloyed layer and reducing the energy level of the first high beam energy too cause growth of the layer. The examiner states that the differences between the patent and the present claims are that depositing an inorganic material containing calcium phosphate such as hydroxylapatite as the desired material, the substrate being of C.P. titanium, titanium alloy or resin and the article such as a dental implant and an orthopedic implant made by the method are not discussed.

The examiner notes that Cotell et al. teach utilizing a medical, dental or orthopedic implant as a substrate for supporting films of hydroxylapatite which contains

calcium phosphate and that the substrate is preferably corrosion resistant and may generally comprise any suitable material, e.g., metal, alloy, ceramic and/or polymer material in any suitable shape and further that the patent teaches that during deposition a suitable ion source can be used to pre-clean substrates in-situ to improve adhesion between the deposited film of biocompatible material and the substrate and/or to densify the material as it is being deposited, the examiner referring to col. 5, lines 59-63.

Motivation relating to biocompatibility and corrosion resistance is noted and the examiner than opines that it would have been obvious to one or ordinary skill in the art at the time the invention was made to have modified Deutchman et al. by depositing an inorganic material containing calcium phosphate such as hydroxylapatite as the desired material, by utilizing C.P. titanium, titanium alloy or a resin as a substrate and by utilizing the substrate as an article such as a dental implant or an orthopedic implant as taught by Cotell et al. because it allows for the production of a film that is biocompatible, allows for providing corrosion resistance and allows for production of articles for short or long term contact with human or animal tissue.

It is submitted that this rejection should be withdrawn for the following reasons.

As noted in applicants' specification (paragraph 003), it is known that biocompatible materials, such as hydroxylapatite (HA), are bioactive and react compatibly with bone which forms a tenacious bond HA. HA also enhances the speed of bone healing around implants. As also noted in the specification, plasma sprayed HA coatings have been successfully used clinically since at least the early 1980s to enhance load transmitting capabilities of orthopedics and dental prosthetic implants placed into bone, however, these coatings have been subject to undesirable limitations, such as a propensity for

infection in cases where plasma sprayed coating extends supra-crestally into the gingival tissue. However, even though Cotell et al. do not rely on plasma spraying techniques, it is submitted that the patent to Cotell et al. would lead one skilled in the art away from considering the Deutchman et al. process. Cotell et al. teach the use of pulsed laser depositions as a means for coating implantable articles, such as medical prosthesis, with biocompatible materials. According to the patent, a vapor of biocompatible coating material is generated by (pulsed) laser deposition and in order to nucleate and grow with the proper composition and structure to be useful as a biocompatible material the vapor is reacted with water at highly elevated temperatures. In all the examples disclosed in the patent, the substrate being coated was heated up to 800 degrees C in a closed reactor in the presence of a high partial pressure (300 mTorr) of oxygen or, in most cases, water. As noted in column 5, lines 30-33, precise temperature control at the surface of deposition is required for many applications. This is accomplished by one or more radiant heaters or a quartz lamp.

This heating is the antitheses of the Deutchman et al. teaching and would not suggest using the process of Deutchman et al. alone or modified. It is submitted that Cotell et al. teach that maintaining the temperature of the substrate being coated at an elevated temperature is important in providing a coating having the proper composition and structure to be useful as a biocompatible material and thus would not suggest using these materials in the process of Deutchman et al. in which no heating is employed or suggested.

It should be noted that although Cotell et al. discuss the use of ion beam irradiation as a means of cleaning the material surface prior to coating and as a means of

densifying the coating, in all six examples the use of ion beam irradiation during the coating growth is not indicated. Further, in an atmosphere of the partial pressure cited in the examples, it would not be possible to propagate an ion beam in the coating reactor (where a vacuum of would be required). Thus Cotell et al. do not teach or suggest the use of any ion assisted coating process to coat implantable articles with biocompatible implantable articles with biocompatible materials, but rather the use of the process as a potential means of cleaning the surface of the implantable substrate material prior to coating by high temperature (pulsed) laser deposition process disclosed.

Claims 1-12 also stand rejected under 35 U.S.C. 103(a) as being unpatentable over Deutchman et al. (U.S. Pat. No. 4,992,298) in view of Imai et al. (Japan 09-301797), the examiner referring to his previous discussion of Deutchman et al. and applies that to the Imai et al. reference. It is stated in the rejection that Imai et al. teach coating an article such as a living body-applicable article with a crystalline calcium phosphate compound film with good adhesion by using vapor evaporation and ion irradiation at the same time and them bringing the film into contact with a pseudo body fluid. The examiner states that the patent teaches that vapor deposition and ion irradiation are jointly used to form a calcium phosphate compound film and concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Deutchman et al. by utilizing an inorganic material along with a substrate of C.P. titanium, titanium alloy or resin and utilizing an article such as a dental implant and an orthopedic implant as taught by Imai et al. because it allows the article to be utilized in a living body. It is respectfully submitted that this rejection should be withdrawn for the following reasons.

Imai et al. are concerned with applying a coating to implantable articles with a coating of crystalline calcium phosphate compounds by immersing the article in an inorganic solution containing calcium and phosphorous. Since crystalline calcium phosphate will not nucleate and grow on most material surfaces directly, Imai et al. pretreat the article in preparation for the immersion coating process. This is accomplished by vacuum evaporation, such as by ion beam spatter vacuum evaporation, along with simultaneous ion irradiation by an ion beam containing inert gases and preferably oxygen in order to densify the film and to attempt to control composition of the film during growth. The pre-treated article is then immersed in the solution to grow the crystalline calcium phosphate having the desired crystallization properties. There is no suggestion in Imai et al. for one skilled in the art to use the Deutchman et al. process which involves depositing a layer on a substrate by sputtering a beam of inert atoms while simultaneously exposing the substrate to another beam of inert ions at a selected energy rate to grow a ballistically alloyed layer and then to continue the another beam at a reduced energy level to cause the growth of a film on the substrate of a final desired thickness as a pretreatment step, for an immersion process to grow crystalline calcium phosphate as the finishing step. It is submitted that the examiner is using applicants' own disclosure for the teaching for making such a modification. Imai et al. stress the importance of providing certain crystalline calcium phosphate compositions and in effect tie their pretreatment step with their immersion coating step in order to obtain their desired composition. Thus one skilled in the art would not be lead by Imai et al. to use the process of Deutchman et al. in attempting to provide their particular crystalline composition.

For the above reasons it is believed that the rejections of claims 1-12 as unpatentable over Deutchman in view of Cotell et al. and in view of Imai et al. should be withdrawn and the claims allowed and such action is respectfully requested.

Respectfully submitted,



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